

**REMARKS**

Claims 29, 54, 55, 57, 61-64, 67 and 69-71 are currently amended. New claims 72 and 73 are added. Claims 1-28, 53 and 56 were previously canceled without prejudice. Claims 29-52, 54-55, and 57-73 are pending in the application with entry of this Amendment. Support for the claim amendments and new claims can be found throughout the originally filed specification and drawings. *See, e.g.*, p. 12, line 27 - p. 13, line 5 (output provided to a user to prompt or notify user to manually initiate breaking of the temporary connection). No new matter has been added. Reconsideration and allowance of the application, as amended, are respectfully requested.

**I. Claims 29-36, 44-46, 54, 55, 57-61, 64 and 65 Are Novel Over Scheldrup**

Independent claim 29 and dependent claims 30-36, 44-46, 54, 55, 57-61, 64 and 65 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 5,669,905 to Scheldrup *et al.* (“Scheldrup”). However, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicants respectfully traverse the rejection, since Scheldrup does not anticipate independent claim 29, as amended, (and, thus, by extension), dependent claims 30-36, 44-46, 54, 55, 57-61, 64 and 65.

Scheldrup does not disclose, teach or suggest the presence of an electrical measurement device that is configured to (i) “monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the implant and delivery member, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location as the delivery member is advanced through the catheter,” and (ii) “generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating that the temporary connection, joined to the implant, has reached the predetermined location” (i.e., before the temporary connection is broken), as required by claim 29. In particular, claim 29, as amended, recites that the electrical measurement device is configured to generate an output that indicates that the temporary connection is at a particular, pre-determined location (but not yet broken), as opposed to indicating a change in an electrical condition that results from, or follows, breaking of the temporary connection.

Scheldrup does not disclose, teach or suggest any such output generated before the temporary connection is broken, i.e., while the implant is still joined to the temporary connection. In contrast, as described by Scheldrup, a change of impedance occurs after, as a direct result of, detachment of a coil, i.e., after a connection has been broken.

The Office Action refers to col. 4, lines 25-33 of Scheldrup to support the rejection and alleges that this section of the cited reference describes an output signal that indicates that a temporary connection is located in a predetermined location and may not necessarily be broken. Office Action (p. 10). However, Scheldrup explains that a change of impedance (in excess of 20%) relative to an average impedance value is used to determine when detachment occurs, i.e., that impedance will suddenly increase as a result of, or following, detachment of the occlusion device so that power input the sacrificial link can be turned off. For example, Scheldrup explains that the actual moment of detachment of the occlusion device, the result of detachment is a sudden or significant change in the monitored AC impedance, and this provides an accurate indication that “an open” has formed and that the occlusion device has become attached from the delivery member. Scheldrup (col. 4, lines 12-15; col. 12, line 49 - col. 13, line 7 (claims 1-6); claim 1 - impedance monitoring circuit). The cited section notes that there may be changes below the “20%” value, but fails to disclose, teach or suggest the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location as the delivery member is advanced through the catheter, the electrical measurement device configured to generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating that the temporary connection, joined to the implant, has reached the predetermined location as recited in claim 29.

The Office Action also refers to col. 7, line 49 - col. 8, line 33, which describes, among other things, determining that a coil detachment has occurred, and then, using a detach indicator (such as a light) to indicate that detachment has already occurred. Scheldrup (col. 8, lines 29-30) (emphasis added). This section also refers to a “Pause Mode” when electrolytic separation has occurred. Scheldrup (col. 7, lines 61-62) (emphasis added).

For reference, and in order to eliminate Scheldrup from further consideration, Applicants note the following determinative sections of Scheldrup that demonstrate that the cited reference is specifically directed to detecting detachment of a coil by breaking of a temporary connection and indicating a change in an electrical condition that results from, or follows, breaking of the temporary connection:

Abstract: (In particular, it deals with a method to predictably determine **the instant of electrolytic detachment** of an embolic device)

Abstract: The invention further includes a method for delivering an embolic device and **detecting its electrolytic separation**.

When a predetermined **change in that impedance** (or amplitude occurs), **which indicates coil detachment**, the DC power is interrupted to minimize or avoid further electrolysis.

Col. 1, lines 17: invention involves a method and apparatus for **detecting electrolytic separation** of an endovascular occlusion device . . .

Col. 3, line 5 (noting previous attempts to **detect coil detachment**)

Col. 3, lines 18-21 (describing known methods for **detecting actual moment of detachment**)

Col. 3, lines 60-63 (need for system that can accurately **detect electrolytic separation**)

Col. 3, lines 66-67 (invention directed to **detecting electrolytic separation**)

Col. 4, lines 12-18 (**detects separation**)

Col. 4, line 34 (method for **detecting electrolytic separation**)

Col. 7, lines 61-62 (In Pause Mode, when electrolytic separation has occurred and the unit has shut off power to the guidewire)

Col. 8, lines 25-26 (electronics **determine that coil detachment has occurred**)

Col. 8, line 53 (**identifies separation**)

Col. 8, line 67 - Col. 9, line 5 (detecting sudden change in signal, which is the **result of detachment**, as described in col. 10, lines 16-34)

Col. 11, lines 55-57 (determine the **instant the occlusion device detaches**)

Col. 11, lines 65-67 (sudden voltage change results from **dissolution of junction**)

In view of these differences, Applicants respectfully submit that Scheldrup does not anticipate claim 29 and respectfully request that the rejection of claim 29 be withdrawn. Dependent claims 30-36, 44-46, 54, 55, 57-61, 64 and 65 depend from and incorporate all of the elements and limitations of independent claim 29, and are therefore also believed novel over Scheldrup.

Further, Scheldrup fails to disclose or suggest “a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed while the

implant is joined to the temporary connection” as recited in claim 54. In contrast, Scheldrup describes a LED that flashes “after detecting a coil detachment.” Scheldrup (col. 8, lines 29-30).

Scheldrup also fails to disclose, teach or suggest “an audio indicator, the electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed while the implant is joined to the temporary connection” as recited in claim 55. Rather, while Scheldrup may disclose emitting beeps, these beeps are emitted after coil detachment has already occurred. Scheldrup (col. 10, lines 33-34).

Still further, Scheldrup fails to disclose or suggest “a controller, the electrical measurement device being configured to provide the output signal to the controller while the implant is joined to the temporary connection, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed” as recited in claim 57. Instead, as discussed above, Scheldrup explains that the impedance changes as a result of, i.e., after, coil detachment has already occurred.

Additionally, as admitted in the Office Action, Scheldrup does not disclose or suggest “an insulative member between the implant and the temporary connection” as recited in claim 58.

Scheldrup also fails to disclose or suggest claims 59-61, which recite limitations related to changes in electrical condition based on a location of a temporary connection relative to a distal end of a catheter and when the temporary connection reaches or passes the distal end of the catheter. Claim 61 is also amended to recite *inter alia* “the electrical condition changing when the temporary connection, while joined to the implant, extends beyond the distal end of the catheter.” In contrast, Scheldrup explains that the change of impedance occurs as a result of detachment of a coil (i.e., dissolving of sacrificial link 106) and that the sacrificial link is not dissolved for 1-10 minutes.

Scheldrup also fails to disclose, teach or suggest claim 64, which was also amended to recite “the temporary connection, while joined to the implant.

## **II. Claim 37 Is Patentable Over Scheldrup and Palermo**

Dependent claim 37 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and U.S. Patent No. 5,250,071 to Palermo (“Palermo”). To establish a *prima facie* case of obviousness of a claim under 35 U.S.C. §103(a), an initial requirement is that all the

claim limitations must be taught or suggested by the prior art. All words in a claim must be considered in judging the patentability of that claim against the prior art.

Palermo is cited for the limited purpose of assertedly disclosing a temporary mechanical connection. Palermo, however, does not cure the deficiencies of Scheldrup with respect to independent claim 29. Consequently, even if the asserted combination were made, the combination would nevertheless fail to disclose each and every limitation of claims 29 and 37. Dependent claim 37, therefore, is also believed patentable over Scheldrup and Palermo.

### **III. Claims 38 and 39 Are Patentable Over Scheldrup and Guglielmi**

Dependent claims 38 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and U.S. Patent No. 5,569,245 to Guglielmi *et al.* (“Guglielmi”). Guglielmi is cited for the limited purpose of assertedly disclosing temporary connections broken by heat and RF radiation. Guglielmi, however, does not cure the deficiencies of Scheldrup with respect to independent claim 29. Accordingly, even if the asserted combination were made, the combination would fail to disclose each and every limitation of claims 29, 38 and 39. Dependent claims 38 and 39, therefore, are also believed patentable over Scheldrup and Guglielmi.

### **IV. Claim 40 Is Patentable Over Scheldrup and Sepetka**

Dependent claim 40 is rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and U.S. Patent No. 5,814,062 to Sepetka *et al.* (“Sepetka”). Sepetka is cited for the limited purpose of assertedly disclosing a connection that is hydraulically broken. Sepetka, however, does not cure the deficiencies of Scheldrup with respect to independent claim 29. Accordingly, even if the asserted combination were made, the combination would fail to disclose each and every limitation of claims 29 and 40. Dependent claim 40, therefore, is also believed patentable over Scheldrup and Sepetka.

### **V. Claims 41-43 and 47-52 Are Patentable Over Scheldrup**

Dependent claims 41-43 and 47-52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup as applied to claim 29. Applicants respectfully submit that the rejection of dependent claims 41-43 and 47-52 under §103(a) is moot in view of the deficiencies of Scheldrup discussed above. MPEP §2143.03. Dependent claims 41-43 and 47-52, therefore, are also believed patentable over Scheldrup.

## **VI. Claims 62, 63 and 67-71 Are Patentable Over Scheldrup and Cheng**

Independent claim 67, dependent claims 62 and 63 (which depend from claim 29) and dependent claims 68-71 (which depend from claim 67) are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and U.S. Patent No. 6,296,636 to Cheng et al. (“Cheng”). Cheng is cited for the limited purpose of assertedly disclosing a comparison circuit that compares a threshold current to a current measured by an electrical measurement device. Cheng, however, does not cure the deficiencies of Scheldrup with respect to independent claim 29 and, therefore, claims 62 and 63 are believed patentable. Further, Scheldrup and Cheng, individually and in combination, fail to disclose, teach or suggest all of the limitations of independent claim 67 (and, thus, by extension), dependent claims 68-71.

For example, the cited references, individually and in combination, fail to disclose, teach or suggest a current measurement device configured to monitor the electrical current as the delivery member is pushed through the catheter, the electrical current being related to a relative position of the temporary connection before the temporary connection is broken, the electrical current increasing from a first current level while the temporary connection is joined to the implant, to a second, higher current level when the temporary connection, joined to the implant, reaches a predetermined location relative to the catheter as required by claim 67. Accordingly, even if the asserted combination were made, the combination would fail to disclose each and every limitation of claim 67. Thus, Applicants respectfully submit that the rejection of dependent claim 67 under §103(a) cannot stand. MPEP §2143.03.

Further, Applicants respectfully submit that the a persons of ordinary skill in the art would not combine Scheldrup and Cheng since Cheng is directed to ablation or coagulation of tissue and limiting the amount of power delivered during electrosurgery, whereas Scheldrup is relates to methods for ensuring endovascular occlusion. (*Cf.* Cheng, col. 3, lines 48-55; Scheldrup, Abstract).

## **VII. Scheldrup Teaches Away From Applicants’ Claims**

Scheldrup also teaches away from claims 37-43, 47-52, 62, 63 and 67-71, all of which stand rejected under 35 U.S.C. §103(a), since these claims recite or incorporate limitations directed to monitoring an electrical condition and generating an output signal, or a current measurement device configured to monitor electrical current and generate an output signal, while

the temporary connection is joined to the implant. In contrast, as discussed above, Scheldrup is directed to detecting a change of impedance following, or resulting from, detachment of a coil. In this regard, Scheldrup describes a configuration that is the opposite of that recited in Applicants' claims and teaches away from Applicants' claims. Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - col. 9, line 5; col. 11, lines 55-57, 65-67).

#### **VIII. New Claims 72 and 73 Are Patentable Over the Cited References**

New dependent claims 72 and 73 depend from respective independent claims 29 and 67 and, therefore, are also believed allowable. Scheldrup also fails to disclose, teach or suggest "wherein the output signal is provided to a user, while the temporary connection is joined to the implant, to allow the user to manually initiate breaking of the temporary connection and release the implant" as recited in claims 72 and 73. Rather, Scheldrup describes detecting changes of impedance resulting from detachment of a coil, i.e., following breaking of a connection and detachment of the coil. Scheldrup is understandably silent as to allowing a user to decide whether and when to break a temporary connection to release an implant since the reference merely describes applying current and electrolytically detaching a coil. Scheldrup (col. 4, lines 10-11; col. 6, lines 23-25).

#### **CONCLUSION**

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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